IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Gerard Wolfe Sormann et al.		
Application No.:	09/786,252	Art Unit:	3762
Filed:	August 13, 2001	Examiner:	Mark Bockelman

For: MEDICAL IMPLANT SYSTEM

DECLARATION UNDER 37 C.F.R. 1.132

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

I, Gerard Wolfe Sormann, declare as follows:

1. I have personal knowledge of the following facts and I make this declaration in support of the prosecution of U.S. Patent Application Serial No. 09/786,252 before the United States Patent and Trademark Office.

2. I am a director of Wolfe Research Pty Ltd, a position I have held for 6 years.

3. My curriculum vitae is attached as Appendix A.

4. I am a co-inventor of the subject matter of the above-identified application and I am familiar with the art and with the prosecution history of this application.

5. I have reviewed the pending Office Action as well as the claims amended in accordance with the Amendment and Request for Continued Examination filed herewith. In particular, the Office Action asserts that U.S. Patent No. 5,967,986 (Cimochowski et al.) teaches a primary controller (Figs. 7-10 and 12), an antenna-based stent device that receives power and transducer selection data from the primary controller to select various transducers to monitor various characteristics such as flow and transmit the results back to

the primary controller, and a monitoring console. In addition, the Office Action asserts that Cimochowski et al. teaches that for deep implants frequencies up to 100 MHz may be used and for shallower implants higher frequencies are used. The Office Action asserts that Cimochowski et al. teaches the use of frequencies up to 1 GHz. Further, the Office Action cites U.S. Patent No. 6,210,347 (Forsell) as teaching the use of GHz frequencies for the transmission of power or data. The Office Action cites U.S. Patent No. 5,170,802 (Mehra) as teaching the use of the stent device of Cimochowski for pacing and stimulating muscles. Finally, the Office Action cites U.S. Patent No. 5,583,510 (Ponnapalli et al.) as teaching the use of a conventional planar omnidirectional antenna.

6. Cimochowski et al. teaches the use of an implant and a controller where there is magnetic inductive coupling between the two units to enable the transmission of energy using a near-field effect. Cimochowski et al. does not teach or suggest to one of ordinary skill in the art to use far-field effects to transmit radiation energy between an implant and controller.

7. Magnetic inductive coupling transfers power by creating a magnetic field about the external device in close proximity to the implanted device such that the implanted coil is within the magnetic field that is created by the external device. The magnetic field then causes an electric current within the implanted coil. It is thus necessary for the implanted device to contain a wire coil and for the implanted device to be placed close to the undersurface of the skin. The magnetic field in the external device may be created by running an electric current through a similar (matching) wire coil in the external device. The greater the electric current passed through the coil, the greater the magnetic field.

8. Energy transfer by magnetic inductive coupling requires the implanted device to be in close proximity to the external device in order to create the coupling effect as the implanted device must remain within the magnetic field of the external device. The effectiveness of this magnetic coupling diminishes as the distance between the coils increases and this may be represented as $1/d^3$, where d is the distance between the two coils. As a result, the device in Cimochowski et al. will only work if the implanted device and the external device are in close proximity.

9. Cimochowski et al. specifically teaches that the higher frequencies are to be used when the implant is only a few millimeters below the skin, and thus, close to the controller. (Col. 12, lines 30-38.) Further, Cimochowski et al. teaches that the dielectric constant of the higher frequencies has little effect on power/data signal coupling. (Col. 12, lines 44-46). Therefore, to one of ordinary skill in the art, Cimochowski et al. only teaches the use of magnetic inductive coupling between the implant and the controller, that is, a near-field effect, even at frequencies up to 1 GHz.

10. Further, Cimochowski et al. teach a device where the external device can only transfer energy to a single implanted device at a time since. Cimochowski et al. could not be used to transfer energy simultaneously to two implanted devices in distant parts of the body. This is because the device in Cimochowski et al. requires that the external device is in close proximity to the implanted device.

11. The Office Action mistakenly interprets the statement at page 8, lines 20-21 of the specification to indicate that coils will act as dipole antennae at higher frequencies. This is not the case. As described above, Cimochowski et al. teaches that the external device and implanted device must be in close proximity, especially at the higher frequencies. As a result, the external

device and the implanted device are still magnetically coupled at the higher frequencies used in Cimochowski et al.

12. In contrast, the present invention does not utilize magnetic inductive coupling for the transmission of energy between the implant and the controller. The present invention utilizes the far field effect of electromagnetic radiation (EMR). EMR transmits energy in a wavelike pattern from a source in all directions and can propagate over distance and through all materials such as tissue and air depending on the energy. The energy of these waves diminishes as the distance from the source increases which can be represented as $1/d$. There is thus much less decrease over distance when compared to $1/d^3$ for magnetic inductive coupling which is used in Cimochowski et al. Thus, the receiving antenna in the present invention does not have to be placed in close proximity to the transmitting antenna. Further, the antenna can be any shape since it is capturing EMR waves and not relying on a magnetic field to transfer electric current.

13. Since the external device in the present invention transmits energy by electromagnetic wave radiation which propagates indefinitely while losing its energy proportionally to $1/d$, it is possible to have the external device and the implanted devices at a distance from each other. One benefit of this is that the single external device can transfer energy to a number of implanted devices. Another benefit is that an implanted device could be implanted deeper in the body.

14. A further benefit is that a person having one or more implanted devices could be mobile within a reasonable range of the external device without having to be in physical contact with the external device. For example, a patient who was sleeping in a bed could be free to move without the implanted device losing communication with the external device. In contrast, Cimochowski et

al. teaches that the internal and external coils need to be closely situated so that they are within each other's magnetic field. As a result, it is important that the patient be positioned so that the implanted and external coils are aligned and thus coupled.

15. The Office Action refers to lines 5 to 8 on page 14 of the specification which refer to "the inductance and capacitance of the wire structure". This phrase refers to physical properties of the wires used in an antenna which affect its ability to capture EMR waves, delivering energy to the implanted device. The wires discussed on page 14 are not involved in magnetic inductive coupling.

16. Further, Cimochowski et al. teaches away from the present invention because it states that the higher frequencies are only to be used when the implant is close to the controller. In the present invention, higher frequencies can be used with greater distance between the implant and the controller, that is a far-field effect, because there is no magnetic inductive coupling between the implant and the controller, that is, near-field effect.

17. Forsell, Mehra, and Ponnapalli et al. do not teach or suggest the present invention alone or in combination with Cimochowski et al.

18. I hereby declare that all statements made herein of my own knowledge are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Dated this 1 day of April, 2004.

GERARD SORMANNI

Name

DR. MERVYN CASS
73 KOOYONG ROAD
CAULFIELD 3161
TEL: 9576 2000
FAX: 9509 2666